MAY 16 2006

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

Medison Co. Ltd.
1003, Daechi-dong, Gangnam-gu,
Seoul 135-280, Korea

Contact Person:
Mr. Kyung-Am, Shim
Regulatory Affairs Manager

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Data Prepared:
April 10, 2006

2. Name of the device:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

SONOACE PICO Diagnostic Ultrasound System

Classification Names:	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3. Identification of the predicate or legally marketed device:

K013627, 11/16/2001, SA8000 Ultrasound system
K043455, 12/21/2004, SA8000 SE Ultrasound system

4. Device Description:

The SONOACE PICO is a general purpose, mobile, software controlled, diagnostic ultrasound system with on-screen display for themal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire ultrasound data and to display the data as B-mode, M-mode, Color Doppler, Pulsed (PW) Doppler, Power Doppler, Harmonic imaging and 3D imaging , or as a combination of these modes on the LCD monitor.

The SONOACE PICO has been designed to meet the following product safety standards:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment y
- NEMA UD 2-2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD 3-2004 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 61157, Declaration of the acoustic output
- ISO10993, Biocompatibility

5. Intended Uses:

The SONOACE PICO system is intended for the following applications:
General, OB, Gynecology, Abdomen, Fetal Heart, Renal, Neonatal, Pediatric, Vascular, Cardiac, Urology, Breast, Small Parts, Musculoskeletal applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. Technological Characteristics:

The SONOACE PICO is substantially equivalent to the SA8000 Diagnostic Ultrasound System, cleared via K013627, and the SA8000 SE Diagnostic Ultrasound System, cleared via K043455. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

END of 510(K) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2006

Medison Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K061213
Trade Name: SONOACE PICO Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: April 27, 2006
Received: May 2, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOACE PICO Ultrasound System, as described in your premarket notification:

Transducer Model Number

C2-4ES	C4-9ED	HL5-9ED
C2-5ET	EC4-9ED	L5-9EC
C3-7ED	EC4-9ES	L5-9EE
C4-7ED	HC2-5ED	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

Section 4.3
INDICATIONS FOR USE

DIAGNOSTIC ULTRASOUND INDICATIONS STATEMENT

510(k) No.: K061213
Device name: SONOACE PICO Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Note 2, 6, 7, 8
	Abdominal	P	P	P		P	Note 1	Note 2, 6, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 7, 8
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 5, 8
	Neonatal Cephalic	N	N	N		N	Note 1	Note 2, 5, 8
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 3, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note1	Note 2, 5, 8
	Musculo-skel. (Superfic.)	P	P	P		P	Note1	Note 2, 5, 8
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P		P	Note1	Note 4
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note1	Note 2, 5, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K031552; E= added under Appendix E
Additional Comments:
Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061213
Device name: C2-4ES with SONOACE PICO Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	N	N	N		N	Note 1	Note 2, 7, 8
	Abdominal	N	N	N		N	Note 1	Note 2, 7, 8
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 5, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P		P	Note1	Note 4
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K031552; E= added under Appendix E
Additional Comments:
Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061213
Device name: C2-5ET with SONOACE PICO Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K043455; E= added under Appendix E
Additional Comments:
Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061213
Device name: C3-7ED with SONOACE PICO Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K013627, K031552, K043455; E= added under Appendix E
Additional Comments:
Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061213

Device name: C4-7ED with SONOACE PICO Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K990970, K012887; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061213

Device name: C4-9ED with SONOACE PICO Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Note 2, 6, 7, 8
	Abdominal	N	N	N		N	Note 1	Note 2, 6, 7, 8
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 5, 8
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 5, 8
	Neonatal Cephalic	P	P	P		P	Note 1	Note 2, 5, 8
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note1	Note 2, 5, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K043455; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061213

Device name: EC4-9ED with SONOACE PICO Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 3, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K031552, K043455; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061218

Device name: EC4-9ES with SONOACE PICO Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined*. (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	Note 2, 8
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 3, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K031552, K013627; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061213
Device name: HC2-5ED with SONOACE PICO Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note1	Note 2, 8
	Abdominal	P	P	P		P	Note1	Note 2, 8
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note1	Note 2, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K031552; E= added under Appendix E
Additional Comments:
Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061213

Device name: HL5-9ED with SONOACE PICO Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic					-		
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 8
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 5, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note1	Note 2, 5, 8
	Musculo-skel. (Superfic.)	P	P	P		P	Note1	Note 2, 5, 8
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note1	Note 2, 5, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K013627, K031552, K043455; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

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Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061213
Device name: L5-9EC with SONOACE PICO Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 8
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 5, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 8
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 8
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K013627; E= added under Appendix E
Additional Comments:
Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061213

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.: K061213
Device name: L5-9EE with SONOACE PICO Ultrasound System
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative (Abdominal, vascular)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 8
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 5, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 8
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 8
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 2, 8
	Other (spec.)							

N= new indication; P= previously cleared by FDA in K043455; E= added under Appendix E
Additional Comments:
Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PWD, B/Color Doppler, B/Power Doppler, B/Color Doppler/PWD, B/Power Doppler/PWD
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D Imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
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